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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/764,127

01/23/2004

Mark Zdeblick

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BOZICEVIC, FIELD & FRANCIS LLP  
(PROTEUS BIOMEDICAL, INC)  
1900 UNIVERSITY AVENUE, SUITE 200  
EAST PALO ALTO, CA 94303

EXAMINER

JOHNSON, SHEVON ELIZABETH

ART UNIT

PAPER NUMBER

3766

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/764,127

Applicant(s)

ZDEBLICK ET AL.

Examiner

Shevon E. Johnson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19, 21-45, 58-60 and 79-87 is/are rejected.
- 7) ☒ Claim(s) 20, 46-57 and 61-78 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/04, 9/04, 2/05, 1/06, 2/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Specification*

1. The disclosure is objected to because of the following informalities: On page 1, lines 8-9, U.S. Patent Application Nos.: 10/\_\_\_\_\_ (Attorney Docket No. 21308-000710US); and 10/\_\_\_\_\_ (Attorney Docket No. 21308-00111US) should be changed to U.S. Patent Application Nos.: 10/764,125 (Attorney Docket No. 21308-000710US); and 10/764,429 (Attorney Docket No. 21308-00111US). Appropriate correction is required.

### *Drawings*

2. The drawings are objected to because of informalities disclosed on PTO-948, appropriate correction is required. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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**4. Claims 1-9, 14-19, 21-25 and 27-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Orth (U.S. Patent No. 5,423,323).**

In regards to claim 1, Orth discloses a method for measuring a cardiac performance parameter, the method comprising: causing a change in at least one of volume and pressure in a heart chamber at a selected time during a heart cycle; measuring a change in at least one characteristic of the heart chamber which occurs in response to the change in at least one of volume and pressure; and calculating at least one cardiac performance parameter based on a ratio of the measured change in the characteristic to the caused change (col. 3, line 28 – col. 5, line 6).

In regards to claim 2, Orth discloses a method wherein causing the change comprises introducing a volume of fluid into the heart chamber during diastole (col. 7, lines 4-20).

In regards to claim 3, Orth discloses a method wherein introducing the volume of fluid comprises releasing the fluid within the heart chamber via one or more apertures in a catheter positioned in the chamber (col. 9, lines 32-41).

In regards to claim 4, Orth discloses a method wherein introducing the volume of fluid comprises inflating an expandable balloon coupled with a catheter positioned in the heart chamber (col. 7, lines 4-20; figs. 1-4).

In regards to claim 5, Orth discloses a method wherein inflating the balloon comprises: inflating the balloon during systole of the heart; and deflating the balloon during diastole of the heart immediately following the systole (col. 7, lines 4-20; figs. 1-4).

In regards to claim 6, Orth discloses a method wherein inflating the balloon comprises: inflate the balloon during diastole of the heart; and deflating the balloon during systole of the heart immediately following the diastole (col. 7, lines 4-20; figs. 1-4).

In regards to claim 7, Orth discloses a method wherein introducing the volume of fluid comprises: inflating a balloon within the heart chamber during systole; deflating the balloon during diastole immediately following the systole; and releasing an amount of fluid within the heart chamber during the diastole (col. 7, lines 4-20; figs. 1-4).

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In regards to claim 8, Orth discloses a method wherein the balloon is deflated by a volume equal to the amount of the released fluid (col. 10, lines 31-41).

In regards to claim 9, Orth discloses a method wherein the balloon is deflated by a volume greater than the amount of the released fluid (col. 10, lines 31-41).

In regards to claim 14, Orth discloses a method wherein causing the change comprises inducing a paroxysmal ventricular contraction (col. 7, lines 10-20).

In regards to claim 15, Orth discloses a method wherein the paroxysmal ventricular contraction is induced by electrical stimulation (col. 7, lines 10-20).

In regards to claim 16, Orth discloses a method comprising measuring the heart cycle using an electrocardiogram device, wherein the selected time during the heart cycle is selected using the electrocardiogram measurement (col. 6, lines 54-56).

In regards to claim 17, Orth discloses a method comprising measuring the heart cycle using at least one sensor on a catheter positioned in the heart chamber, wherein the selected time during the heart cycle is selected using the sensor measurement (col. 6, lines 54-56).

In regards to claim 18, Orth discloses a method wherein the change in the cardiac characteristic is measured immediately after causing a change in at least one of volume and pressure (col. 6, lines 18-33).

In regards to claim 19, Orth discloses a method wherein the change in the cardiac characteristic is measured during at least a portion of the heart cycle after the change in at least one of the volume and pressure (col. 6, lines 18-33).

In regards to claim 21, Orth discloses a method wherein measuring the change comprises measuring a change in at least one pressure within the heart chamber (col. 7, line 34 – col. 8, line 18; col. 15, lines 24-51).

In regards to claim 22, Orth discloses a method wherein measuring the change in pressure comprises measuring a change in end-diastolic pressure and a change in end-systolic pressure (col. 7, line 34 – col. 8, line 18; col. 15, lines 24-51).

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In regards to claim 23, Orth discloses a method wherein calculating the at least one parameter comprises calculating a cardiac pressure gain, comprising: calculating a first difference between a first end-systolic pressure and a second end-systolic pressure; calculating a second difference between a first end-diastolic pressure and a second end-diastolic pressure; and dividing the first difference by the second difference (col. 7, line 34 – col. 8, line 18; col. 15, lines 24-51).

In regards to claim 24, Orth discloses a method comprising providing at least one of the end-diastolic pressures, the end-systolic pressures and the cardiac pressure gain for display on a display device (col. 7, line 34 – col. 8, line 18; col. 9, lines 55-57).

In regards to claim 25, Orth discloses a method wherein the providing step comprises providing data in the form of a plot, with at least one end-diastolic pressure on one axis of the plot and at least one end-systolic pressure on a perpendicular axis of the plot (col. 7, line 34 – col. 8, line 18; col. 9, lines 55-57).

In regards to claim 27, Orth discloses a method wherein measuring the change comprises measuring a change in at least one volume within the heart chamber (col. 7, line 34 – col. 8, line 18).

In regards to claim 28, Orth discloses a method wherein measuring the change comprises measuring a change in end-diastolic volume and a change in end-systolic volume (col. 7, line 34 – col. 8, line 18).

In regards to claim 29, Orth discloses a method wherein calculating the at least one parameter comprises calculating a volume reserve comprising: calculating a first difference between a first end-systolic volume and a second end-systolic volume; calculating a second difference between a first end-diastolic volume and a second end-diastolic volume; and dividing the first difference by the second difference (col. 7, line 34 – col. 8, line 18).

In regards to claim 30, Orth discloses a method comprising providing at least one of the end-diastolic volumes, the end-systolic volumes and the volume reserve for display on a display device (col. 7, line 34 – col. 8, line 18; col. 9, lines 55-57).

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In regards to claim 31, Orth discloses a method wherein the providing step comprises providing data in the form of a plot, with at least one end-diastolic volume on one axis of the plot and at least one end-systolic volume on a perpendicular axis of the plot (col. 7, line 34 – col. 8, line 18; col. 9, lines 55-57).

In regards to claim 32, Orth discloses a method wherein measuring the change comprises measuring a change in a left ventricular end-diastolic volume and a change in a left ventricular end-systolic volume (col. 7, line 34 – col. 8, line 18).

In regards to claim 33, Orth discloses a method wherein measuring the change comprises measuring a change in at least one pressure and a change in at least one volume within the heart chamber (col. 7, line 34 – col. 8, line 18; col. 15, lines 24-51).

In regards to claim 34, Orth discloses a method wherein measuring the change comprises measuring a change in end-diastolic volume and a change in end-diastolic pressure (col. 7, line 34 – col. 8, line 18; col. 15, lines 24-51).

In regards to claim 35, Orth discloses a method further comprising providing pressure and volume data as a plot, with at least one volume on one axis of the plot and at least one volume on a perpendicular axis of the plot. (col. 7, line 34 – col. 8, line 18; col. 9, lines 55-57).

#### ***Claim Rejections - 35 USC § 103***

**5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**6. Claims 36-39 and 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orth (U.S. Patent No. 5,423,323) in view of Paolocci, Nazareno, et al., "Positive inotropic and lusitropic effects of HNO/NO<sup>-</sup> in failing hearts: Independence from beta-adrenergic signaling", PNAS, vol. 100, No. 9, (Apr. 29, 2003), 5537-5542.**

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In regards to claims 36-39 and 42-45, Orth discloses the method substantially as claimed except lusitropic and inotropic stiffness. However, Paolocci teaches lusitropic and inotropic stiffness (pg. 5538, Hemodynamic Analysis; pg. 5539, HNO/NO<sup>-</sup> Augments Inotropy and Lusitropy of Failing Heart; pg. 5540-41, Discussion).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Orth by incorporating the method of or concept of lusitropic and inotropic stiffness as taught by Paolocci in order to provide improved monitoring of cardiac performance parameters.

In regards to claim 40, Orth discloses a method wherein measuring the change comprises measuring a change in end-diastolic volume and a change in end-diastolic pressure (col. 7, line 34 – col. 8, line 18; col. 15, lines 24-51).

In regards to claim 41, Orth discloses a method further comprising providing pressure and volume data as a plot, with at least one volume on one axis of the plot and at least one volume on a perpendicular axis of the plot. (col. 7, line 34 – col. 8, line 18; col. 9, lines 55-57).

**7. Claims 10-13, 58-60 and 79-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orth (U.S. Patent No. 5,423,323) in view of Sekins et al. (U.S. Patent No. 5,158,536).**

In regards to claims 10-13 and 58-60, Orth discloses the method substantially as claimed except for a hydrophone and a change in flow rate. However, Sekins teaches a hydrophone (col. 33, lines 7-20, 47-49; col. 37, lines 13-20) and a change in flow rate (col. 13, lines 17-29; col. 25, lines 51-64; col. 37, lines 4-12).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Orth by incorporating a hydrophone and a change in flow rate as taught by Sekins in order to causing a change in at least volume or pressure to effect a parameter of the heart chamber.

In regards to claim 79, Orth discloses the system for measuring one or more parameters of a heart, the system comprising: a catheter comprising at least one sensor and at least one actuator for introducing a known volume of fluid into at least one chamber of the heart at a selected time

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during a heart cycle to effect a volume change in the heart chamber; a fluid source coupled with the catheter for providing fluid to the actuator; and a processor coupled with the catheter for processing data sensed by the at least one sensor (col. 6, line 34–66; col. 8, line 19 – col. 10, line 24).

In regards to claim 80, Orth discloses a system wherein the at least one sensor comprises at least one of a pressure sensor and a volume sensor (col. 4, line 42 – col. 10, line 24).

In regards to claim 81, Orth discloses a system wherein the at least one sensor further comprises at least one of a flow sensor for measuring blood flowing from the heart and a vascular pressure sensor for measuring pressure in a vessel extending from the heart (col. 4, line 42 – col. 10, line 24).

In regards to claim 82, Orth discloses a system wherein the at least one flow sensor or pressure sensor is disposed in a location to measure flow or pressure in at least one of an aorta, a pulmonary artery, and a coronary artery (col. 4, line 42 – col. 10, line 24).

In regards to claim 83, Orth discloses a system wherein the at least one sensor comprises at least one hydrophone (col. 33, lines 7-20, 47-49; col. 37, lines 13-20).

In regards to claim 84, Orth discloses a system wherein the at least one sensor comprises at least one ultrasound transducer (56, 110) for measuring a distance within a chamber of the heart (col. 9, lines 11-23).

In regards to claim 85, Orth discloses a system wherein the at least one ultrasound transducer (56, 110) comprises: a first pair of ultrasound transducers coupled with the catheter in parallel with a longitudinal axis of the catheter for measuring a first distance between the transducers and the wall of the chamber of the heart; a second pair of ultrasound transducers coupled with the catheter in an orientation 90-degrees rotated from the first pair of transducers for measuring second and third distances to a wall of the heart chamber; and a third pair of ultrasound transducers coupled with the catheter in an orientation 90-degrees rotated from the first and second pairs of transducers for measuring fourth and fifth distances to a wall of the heart chamber (col. 9, lines 11-23).

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In regards to claim 86, Orth discloses a system wherein the at least one actuator comprises at least one of a fluid outlet port and an expandable balloon, the expandable balloon being expandable by introducing the fluid into the balloon (col. 8, lines 19-43).

In regards to claim 87, Orth discloses a system further comprising an electrocardiogram device coupled with the processor 84 for measuring the heart cycle (col. 8, lines 44-55).

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***Allowable Subject Matter***

8. Claims 20, 46-57 and 61-78 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shevon Johnson whose telephone number is (571) 272-2010. The examiner can normally be reached on M-F (8 a.m. - 4:30 p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shevon Johnson  
Art Unit 3766

  
Robert Pezzuto  
Supervisory Patent Examiner  
Art Unit 3766